

REMARKS:

Applicant appreciates the Examiner's attention to the examination of the present application. Applicant believe that the brief remarks contained herein will assist the Examiner in understanding the distinctions between the claimed invention and the cited prior art references, and will show that the current claims are patentable over those references.

• **Status of the Claims**

Claims 1-45 and 64-72 are pending in the present application, claims 46-63 and 73-77 are withdrawn.

• **35 U.S.C. §103**

In the Office Action dated January 17, 2007, the Examiner has rejected claims 1-45 and 64-72 as being obvious in light of Osbakken et al. (U.S. Patent Publication No. 2002/0061281) in view of Gray (U.S. Patent No. 5,698,558) and further in view of Fust (U.S. Patent No. 6,344,210).

The claimed invention includes a composition for the non-addictive treatment of rhinitis, comprising "effective amounts of a suitable nasal decongestant; a suitable corticosteroid; and a suitable anticholinergic agent."

Unlike Applicants' claimed compositions, Osbakken et al. describes compositions and methods for treating chronic sinusitis. Chronic sinusitis differs from rhinitis; it is a distinct condition; it has distinct pathology; and it is treated in a distinct manner. For example, while the claimed composition for treating rhinitis includes a suitable anticholinergic agent, anticholinergic agent, such as antihistamines having an anticholinergic effect, are actually contraindicated for chronic sinusitis because they decrease mucus production, i.e., have a drying effect, which impairs sinus drainage. See e.g., attached excerpts from "Diagnosis and treatment of respiratory

illness in children and adults" from the National Guideline Clearinghouse (http://www.guideline.gov/summary/summary.aspx?ss=15&doc_id=10622&nbr=5564); and "A practical guide for the diagnosis and treatment of acute sinusitis, Can J. Med. 156(6 supp.) S1-S14 (1997) (<http://mdm.ca/cpgsnew/cpgs/sinus/index.htm>). One of ordinary skill in the art would not have included an anticholinergic agent in a composition for treating chronic sinusitis because such agents were contraindicated for chronic sinusitis.

Osbakken et al. describes compositions including an anti-infective agent for treating chronic sinusitis. Although the Osbakken reference includes a laundry list of other ingredients that could be combined with the anti-infective agent, it does not make the claimed invention obvious because the contraindication of anticholinergic agents for chronic sinusitis would have led one of ordinary skill in the art away from selecting a composition including an anticholinergic agent. See e.g., In re Baird, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994) (Finding that a reference disclosing many compounds does not render obvious a claim to a few of the disclosed compounds, "particularly when that disclosure indicates a preference leading away from the claimed compounds.").

Indeed, the intended purpose of Osbakken et al., to provide an effective treatment for chronic sinusitis, would have been rendered unsatisfactory by including an anticholinergic agent in the composition for treating chronic sinusitis because the drying effect of the anticholinergic agent would interfere with the drainage of mucous from the sinuses. See e.g., In re Gordon, 773 F.2d 900 (Fed. Cir. 1984); MPEP, Eighth Edition, Rev. 5, Aug. 2006, §2143.01, V (discussing rendering the prior art unsatisfactory for its intended purpose). It is thus clear that one skilled in the art would not have included an anticholinergic agent in the sinusitis-treating compositions of the Osbakken et al. reference, and thus Osbakken et al. cannot be fairly characterized as making

obvious the claimed composition including an anticholinergic agent, and indeed teaches away from the presently claimed invention.

Moreover, Gray and Fust cannot be used to overcome the deficiencies of Osbakken et al. with regard to anticholinergic agents because these references similarly teach away from the present compositions. In particular, Gray teaches away from the use anticholinergic agents by disclosing a composition for treating rhinitis that "avoids/s adverse effects, including, ... anticholinergic effects." (Col. 1, Lines 23-26; emphasis added). See e.g., KSR Int'l Co. v. Teleflex Inc., 550 U.S. __ (2007) ("[W]hen the prior art teaches away from combining certain known elements...a successful means of combining them is more likely to be nonobvious." (citing United States v. Adams, 383 U.S. 39, 51-52 (1966))). Fust et al. describes a composition for "freshening sinus cavities" and is thus far afield from the present claims and does not include mention of anticholinergic agents.

As such, the combination of Osbakken et al, Gray, and Fust cannot be fairly characterized as rendering obvious the claimed invention, and the Examiner's rejection on the basis of these references is respectfully traversed and should be withdrawn.

In light of the foregoing remarks, Applicant respectfully requests allowance of all claims now pending in this Application.

Respectfully submitted,



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From "Diagnosis and treatment of respiratory illness in children and adults", National Guideline Clearinghouse; See http://www.guideline.gov/summary/summary.aspx?ss=15&doc_id=10622&nbr=5564

48. Home Self-Care

Patients who are in generally good health and only mildly ill may be appropriate candidates for home care/phone management of presumed acute sinusitis. Both the patient and the provider should be comfortable with home care/phone management. The following factors are also supportive of home care/phone management:

- Established patient (has been seen by primary care physician within the past year)
- History of previous sinusitis treated successfully
- Earlier visit with viral upper respiratory infection that has progressed to probable acute sinusitis

The patient should be instructed to implement the following comfort and prevention measures:

Home Self-Care Measures

Maintain adequate hydration (drink 6 to 10 glasses of liquid a day to thin mucus)

Steamy shower or increase humidity in the home.

Apply warm facial packs (warm wash cloth, hot water bottle, or gel pack) for 5 to 10 minutes three or more times per day

Acetaminophen, ibuprofen, aspirin as needed

Saline irrigation (saline nose drops, spray to thin mucus)

Decongestants (topically or orally)

- Pseudoephedrine HCl (e.g., Sudafed) 60 mg every 4 to 6 hours, not to exceed four doses per 24 hours.
- Decongestant nasal sprays for no longer than three days, e.g., oxymetazoline (Afrin), phenylephrine HCl (Neosynephrine)

→Antihistamines

→Antihistamines are not recommended for the treatment of sinusitis because they cause further inspiration of secretions.

Adequate rest

Sleep with head of bed elevated.

Avoid cigarette smoke and extremely cool or dry air.

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POTENTIAL HARMS

Rapid strep-test can render false positive results.

Adverse Effects Associated with Medications

- *Over-the-counter nasal sprays and decongestants* have potential side effects. Adverse effects of oral decongestants include irritability, tremor, insomnia, tachycardia, and hypertension.
- *Antibiotics* cause side effects such as gastrointestinal discomfort, diarrhea, allergic reactions, diaper rash, and yeast infections. Unnecessary use of antibiotics can lead to the development of antibiotic-resistant strains of bacteria.
- *Aspirin* use is associated with Reye's syndrome.
- The most common side effects of *intranasal corticosteroids* are nasal irritation (dryness, burning and crusting) and mild epistaxis. Documented systemic side effects are rare. Nasal septal perforation has been reported. The Food and Drug Administration (FDA) reviewed data that suggested growth may be temporarily slowed in children.
- →**Common side effects of the first-generation antihistamines** include somnolence, diminished alertness and anticholinergic effects such as dry mouth, blurred vision and urinary retention. They can also cause central nervous system impairment and impair driving performance. The *second-generation antihistamines* are less sedating and cause less central nervous system impairment because they do not cross the blood brain barrier well. Side effects of *topical antihistamines* include drowsiness and bitter taste.
- Adverse effects of *cromolyn* are minimal and include nasal irritation, sneezing, and unpleasant taste.
- Side effects of *anticholinergics* include epistaxis, blood-tinged mucus, nasal dryness, dry mouth and throat, dizziness, ocular irritation, blurred vision, precipitation or worsening of narrow angle glaucoma, urinary retention, prostatic disorders, tachycardia, constipation, and bowel obstruction.
- Side effects of *ophthalmic medications* (except corticosteroids) are generally mild and include a brief stinging burning sensation.
- *Immunotherapy injections* are associated with a risk of anaphylaxis during the buildup or maintenance phase of treatment.

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CONTRAINDICATIONS

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→**Antihistamines are contraindicated for patients with recurrent or chronic sinusitis as they may cause ciliary paresis and drying of secretions, thereby impairing sinus drainage.**

From "A practical guide for the diagnosis and treatment of acute sinusitis"; See
<http://ndm.ca/cpgsnew/cpgs/sinus/index.htm>

A practical guide for the diagnosis and treatment of acute sinusitis

Donald E. Low, MD; Martin Desrosiers, MD; James McSherry, MB, ChB; Gary Garber, MD; John W. Williams Jr., MD; Huguette Rémy, MD; Ronald S. Fenton, MD; Vito Forte, MD; Meyer Balter, MD; Coleman Rotstein, MD; Carl Craft, MD; Jacques Dubois, PhD; Godfrey Harding, MD; Melvin Schloss, MD; Mark Miller, MSc, MD; R. Andrew McIvor, MSc, MD; Ross J. Davidson, PhD

Can Med Assoc J 1997;156(6 suppl):S1-S14

* * *

Adjunct therapy

Decongestants

Although there are no published placebo-controlled studies of decongestants, these medications are often included in the treatment of acute sinusitis [2,99,100].

The nasal spray decongestants phenylephrine hydrochloride (0.5%) and oxymetazoline hydrochloride (0.05%) are frequently used to treat acute sinusitis. Phenylephrine spray should be used 3 or 4 times daily for 3 days, but no longer than 1 week [12]. Oxymetazoline spray should be used 2 or 3 times a day, but no longer than 3 to 4 days. Patients who use either agent more frequently or for longer periods than recommended are at risk of rebound vasodilation.

Oral decongestants (pseudoephedrine and phenylpropanolamine) are alpha-adrenergic agonists that reduce nasal blood flow. Theoretically, oral preparations can penetrate the ostiomeatal complex, where topical agents may not penetrate effectively [12]. The use of oral decongestants has been shown to improve nasal patency [101]. As well, Melen and coworkers [33] have demonstrated that these agents can increase the functional diameter of the maxillary ostium. Some oral decongestants are available in combination with mucoevacuants, which may help to thin secretions and facilitate drainage.

→Antihistamines

Antihistamines have not proven to be effective in the management of acute sinusitis and theoretically may be harmful. Because of their anticholinergic action, antihistamines can cause dryness of mucosal membranes and may interfere with the clearance of purulent mucous secretions [12]. Although no controlled studies have examined the role of antihistamines in the treatment of sinusitis, the participants of the Canadian Sinusitis Symposium have recommended that antihistamines not be used to treat acute sinusitis (level III evidence).